K953681

REVISED 510(k) SUMMARY

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Proprietary names: Therapeutic Plasma Exchange (TPE) Protocol
List No. 780 Therapeutic Plasma Exchange Set (225 ml Latham bowl) for use with the MCS®+ (List Nos. 7000 and 8100)
List No. 781 Therapeutic Plasma Exchange Set (125 ml Latham bowl) for use with the MCS+ (List Nos. 7000 and 8100)
List No. 980 Therapeutic Plasma Exchange Set (225 ml Latham bowl) for use with the MCS+ (List No. 9000)
List No. 981 Therapeutic Plasma Exchange Set (125 ml Latham bowl) for use with the MCS+ (List No. 9000)

Classification name: automated (centrifugal) blood separator

Common names: therapeutic disposable collection sets

Predicate devices:

Product	**Predicate Device**
MCS/MCS+ (MCS List No. 7000) (MCS+ List Nos. 8100 and 9000)	COBE Spectra™ Single Needle Access Accessory System for Therapeutic Plasma Exchange (**BK900105**)
List Nos. 780 and 980 Therapeutic Plasma Exchange Sets (225 ml bowl)	COBE Single Needle Access disposable set: Blood Tubing Set, List No. 777000-100 Single Needle bag and "Y", List No. 777000-100 Return Flow Control Assembly, List No. P951000-000 (**BK900105**)
List Nos. 781 and 981 Therapeutic Plasma Exchange Sets (125 ml bowl)	COBE Single Needle Access disposable set: Blood Tubing Set, List No. 777000-100 Single Needle bag and "Y", List No. 777000-100 Return Flow Control Assembly, List No. P951000-000 (**BK900105**)

DEVICE DESCRIPTION

Equipment

The MCS and MCS+ systems have not been physically modified in any significant manner from the systems reviewed by the FDA under 510(k) BK900027 and BK930013, respectively, relative to standard pumps, centrifuge, electromechanical systems and donor safety monitoring systems.

Sterile Single-Use Disposable Sets

List No. 780 Therapeutic Plasma Exchange Set (225 ml Latham bowl)
Consists of a patient harness, a 225 ml centrifuge blood separation chamber (Latham bowl) and a collection harness (tubing distal to bowl) all of which are connected during the manufacturing process. A detached 5 liter plasma bag is also included. This disposable set is for use with the MCS+ (List Nos. 7000 and 8100).

List No. 781 Therapeutic Plasma Exchange Set (125 ml Latham bowl)
Consists of a patient harness, a 125 ml centrifuge blood separation chamber (Latham bowl) and a collection harness (tubing distal to bowl) all of which are connected during the manufacturing process. A detached 5 liter plasma bag is also included. This disposable set is for use with the MCS+ (List Nos. 7000 and 8100).

List No. 980 Therapeutic Plasma Exchange Set (225 ml Latham bowl)
Consists of a patient harness, a 225 ml centrifuge blood separation chamber (Latham bowl) and a collection harness (tubing distal to bowl) all of which are connected during the manufacturing process. A detached 5 liter plasma bag is also included. This disposable set is for use with the MCS+ (List No. 9000).

List No. 981 Therapeutic Plasma Exchange Set (125 ml Latham bowl)
Consists of a patient harness, a 125 ml centrifuge blood separation chamber (Latham bowl) and a collection harness (tubing distal to bowl) all of which are connected during the manufacturing process. A detached 5 liter plasma bag is also included. This disposable set is for use with the MCS+ (List No. 9000).

Operating Protocol Summary

The MCS and MCS+ systems and associated disposable sets are used to perform therapeutic plasma exchange ("TPE") as briefly summarized below.

Protocol options. There are four TPE disposable options which are available: List Nos. 780 and 980 have a 225 ml Latham bowl and List Nos. 781 and 981 have a 125 ml Latham bowl. The smaller bowl size is used when the attending physician desires to minimize the total extracorporeal blood volume (volume temporarily out of circulation) during each processing cycle. The TPE protocol also accommodates the addition of a secondary access site for separate, continuous fluid replacement.

Preparation. The disposable set is loaded on the MCS or MCS+ system by the operator and primed with anticoagulant. With single access, the replacement fluid

bag(s) is/are also spiked. When continuous fluid replacement is desired, replacement fluid is connected to a separate intravenous line and pumped. Thereafter the line is connected to the second lumen of a catheter (if dual-lumen) or to a second access intravenous line for gravity re-infusion.

DRAW/RETURN. Blood is pumped from the patient through the tubing directly into the Latham bowl where the components are separated by centrifugation. The plasma exits the top of the bowl and is directed to the collection bag. The system continuously monitors the outflow of the bowl through optical sensors; when the platelet-rich layer ("buffy coat") is detected, the DRAW phase stops. The blood pump reverses and the RETURN phase begins. The remaining contents of the bowl are returned to the patient with replacement fluid (if not being administered via a secondary access site). When the bowl has emptied, the next DRAW phase begins. The number of DRAW/RETURN cycles required to complete the procedure depends upon the target volume of plasma to be removed.

Intended Use

TPE is performed using the Haemonetics MCS/MCS+ system to remove a significant quantity of platelet poor plasma and replace it with a solution as determined by the attending physician.

Clinical Tests

Haemonetics sponsored clinical evaluations to perform TPE using the MCS with the associated disposable sets.

Briefly, TPE was performed on 30 subjects for over 100 procedures using the AABB Guidelines for Therapeutic Hemapheresis (1993). Subjects were selected from patients for whom TPE was prescribed by their physician. Although enrolled, three subjects were not included in the data analysis because their status as transplant patients put them outside the disease states described by the protocol. The number of procedures and replacement fluids were at the discretion of the attending physician. Patient vital signs, fluid intake/output and extracorporeal volumes were monitored. Blood samples were collected pre- and post-procedure and 18-30 hours post-procedure for sampling. Parameters measured include pre- and post-therapy platelets counts, pre- and post-procedure LDH levels, pre-, post- and18 hour-post procedure hemoglobin and hematocrit, platelet counts, LDH, IgA, IgG and IgM levels, and pre- and post-haptoglobins.

Additionally, a similar, but smaller study was conducted on healthy donors using the MCS+ (LN9000).

The data indicates that the Haemonetics Therapeutic Plasma Exchange protocol and the associated disposables can be performed safely and effectively.

Conclusion

TPE performed using the MCS or MCS+ system with the associated disposable set is substantially equivalent to TPE as performed using marketed devices.